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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,261	07/11/2007	Lars Michael Larsen	LARSEN 5	6440

1444 7590 08/31/2010

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EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
08/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,261	LARSEN, LARS MICHAEL	
	Examiner	Art Unit	
	ZOHREH A. FAY	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *59-115* is/are pending in the application.

4a) Of the above claim(s) *62 and 80-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59-61,63-79 and 108-115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/13/2007; 5/20/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 59-61 and 63-78 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating non-proliferative diabetic retinopathy, does not reasonably provide enablement for preventing diabetic retinopathy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are:

1) The nature of the invention:

The claims are drawn to a method of preventing or treating non-proliferative retinopathy using a medicament comprising a compound capable of inhibiting the visual cycle.

2) The state of the prior art:

The relative sill of those in the art is high, that of an MD or PHD. That factor is outweighed, however by the unpredictable nature of the art. The state of the art does not recognize that the prevention of diabetic retinopathy. The state of the art is directed to the treating, maintaining or improving diabetic retinopathy, but does not recognize the prevention of non-proliferative diabetic retinopathy. See attached article by Mayo Clinic.

3) The relative skill of those in the art:

The relative skill of those in the art is high.

4) The predictability or unpredictability of the art:

The unpredictability of pharmaceutical and chemical art is high.

5) The breath of the claims:

The claims are very broad. Since the instant specification provides no limiting definition of the term "prevention", the term will be interpreted expansively. The tem "prevention" might vary widely in meaning from "preventing" a disease from occurring to "preventing" it from progressing. Nor is the term limited by any time frame.

The claims are thus very broad insofar as they suggest that one will not experience the disease when taking the claimed agent; that should one get the disease , it will not worsen, or that following its treatment, it will not recur. While such "prevention" might theoretically be possible under stoically controlled laboratory conditions, as a practical matter it is nearly impossible to achieve the "real world" in which patient live.

6) The amount of direction or guidance provided:

The specification, including the working examples provides no direction for "preventing" non-proliferative diabetic retinopathy.

7) The presence or absence of working examples;

The examples set forth in the specification are drawn to the treatment of the claimed conditions induced by different factors. There are no examples set forth to demonstrate the "prevention" of the claimed conditions.

8) The quantity of experimentation necessary;

Applicant fails to provide guidance and information sufficient to allow the skilled artisan to ascertain how to "prevent" non-proliferative diabetic retinopathy. Absent such guidance and information, one skilled in the art would have to blindly and empirically experiment, with no reasonable prior expectation of success being present. Accordingly, the instant claims do not comply with the enablement requirement of 112 first paragraph, since to practice the claimed invention in its "full scope" a person of ordinary skill in the art would have to engage in undue experimentation with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-61 and 63-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to using "at least one compound" or "prodrugs" being used for treating of preventing non-proliferative diabetic retinopathy. The specification discloses some compounds within the scope of what is claimed. However, there is no evidence that all the compounds and their prodrugs being used for retinopathy were known to the applicant. Therefore,

the artisan would not have accepted that applicant was in possession of the claimed method of use.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 59-62 and are rejected under 35 U.S.C. 102(b) as being anticipated by Oikawa et al.

Oikawa et al. teach the use of the compounds within the scope of formula I for the treatment of diabetic retinopathy. The above reference makes clear that the claimed compounds have been previously used for the treatment of diabetic retinopathy. See the entire document.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim59-61, 63-79 and 108-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campochiaro et al. (US 5,824,685) in view of Oikawa et al. (submitted by the applicant).

Campochiaro et al. teach the use of the claimed retinoids, such as, Formula V for the treating proliferative retinopathy. See the abstract, column 3, lines 49-64, column 4, lines 30-65, claims 1-12 and table 3. Campochiaro et al. differs from the claimed invention in using the compounds for the treatment of non-proliferative diabetic retinopathy. Oikawa et al. teach the use of the compounds within the scope of formula I for the treatment of diabetic retinopathy. The above reference makes clear that the genus of compounds of Formula V, have been previously used for the treatment of diabetic retinopathy. See the entire document. It would have been obvious to a person

skilled in the art to use compound of formula V for the treatment of diabetic retinopathy, motivated by the teachings of Oikawa et al., which teach the genus of compound V has been previously used for the treatment of diabetic retinopathy. It would have been further obvious to use the compounds of Campochiaro et al. for the treatment of diabetic retinopathy, considering that diabetic retinopathy is an angiogenic proliferative disease, and the use of the claimed compounds for the treatment of proliferative retinopathy is expected to be useful for the treatment of diabetic retinopathy. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 59-61, 63-70 and 108-115 are properly rejected under 35 U.S.C. 103 (a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF
/Zohreh A Fay/
Primary Examiner, Art Unit 1627